

Consent Form

Title of Research Study: Evaluating Diet, Food Insecurity, and Food Purchasing Outcomes of a Full-Service Mobile Food Market with a Cluster Randomized Trial

Investigator Team Contact Information: Melissa Horning PhD

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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A video of this document in ASL is available at: z.umn.edu/ASLMobileMarketStudy

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

The goal of research is to learn new things in order to help people in the future. Researchers learn things by following the same plan with a number of people, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped joining a research study.

Why am I being invited to join this research study?

We are asking you to join this research study because you do most of the grocery shopping for your household and you live in one of the communities that the Twin Cities Mobile Market will be visiting. You are also being asked because you said you would be likely to visit the Mobile Market if it came to your community.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you join is up to you.
- You can choose not to join.
- You can agree to join and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

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Why is this research being done?

The Twin Cities Mobile Market comes to communities that may have less access to low-cost and high quality food. This study is being done to learn more about the Twin Cities Mobile Market and if it changes what kind of food people eat and buy. We also want to learn if the Mobile Market changes peoples' worries about whether they have enough food.

How long will the research last?

We expect that you will be in this research study for about one year.

What will I need to do to participate?

You will be asked to complete surveys about yourself and your thoughts on the Mobile Market, send us information about the fruits and vegetables you buy, and talk with us about the foods you've eaten.

More information about the study activities can be found under "What happens if I say 'Yes, I want to join this study?'"

Is there any way that being in this study could be bad for me?

There is a very small chance that someone could see the information we collect about you. We do our best to keep any data we collect from you safe by following the University of Minnesota's privacy policies and using software that is secure. But absolute confidentiality cannot be guaranteed.

We will also be asking you questions about things that may make you feel uncomfortable, such as questions about if your household has enough to eat. You do not need to answer any questions you feel uncomfortable answering. If you feel worried about not having enough to eat, you will find contact information for Hunger Solutions in your study folder. This organization can help you identify local food shelves and other food assistance programs. If you need help contacting them, we will help you do that.

Will being in this study help me in any way?

Being in this study may not help you and we cannot promise that your participation will help other people. But because this study will help us learn more about how the Mobile Market impacts people in your community, it's possible that someone in your community, or in a community like yours, may be helped in the future.

What happens if I do not want to be in this research?

You do not have to join this research study if you do not want to. The Mobile Market will still be available to you even if you choose not to be a part of this study.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We would like to have about 264 people in our study.

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What happens if I say “Yes, I want to join this study”?

If you choose to be in this study, we will ask you to complete the following study activities:

Information about yourself: At the start of the study, we would like to collect some information about who you are (such as your age, gender, race and ethnicity).

Surveys: At both the start of the study and at follow-up data collection (after the Mobile Market has finished 6 months of weekly visits to the communities who get the mobile market first), we will ask you to complete surveys on topics such as the way you access, shop, and cook food, your health, and whether or not your household could afford enough food.

Food Interviews: At both the start of the study and at follow-up data collection, we will ask to talk with you 3 times to learn about the food you ate the day before.

Fruit & Vegetable Booklets: At both the start of the study and at follow-up data collection, we will ask you to record the fruits and vegetables you get for 4 weeks using booklets we give you. Each time you get groceries during these 4 weeks, we would like you to write down the fruit and vegetable items you got in the booklet. At the end of each week, you’ll mail the booklet to us. You will be given pre-paid envelopes and additional instructions on how to do this.

As part of this study, your community will fall into one of two groups. One group of communities will have the Mobile Market start visiting their area soon (in the next couple of months). The other group of communities will have the Mobile Market visit their area after about a year. When the Mobile Market starts visiting your community, it will come on a weekly basis. The communities that are chosen to have the Mobile Market first will be chosen at random (like the flip of a coin).

If your community is chosen to have the Mobile Market right away, there will be 2 additional activities:

Participate in the “Market Members” program: We will ask you to take part in the “Market Members” program. We would like you to make sure to let the cashier know each time you shop at the Mobile Market that you are part of the program. The Market Members program is like a frequent shopper card for the Mobile Market. It will give you discounts at the Mobile Market after you have made a certain number of shops. Joining the Market Member program also keeps track of what you buy, how much you spend, and how often you visit the Mobile Market. You do not have to be in this study to join the Market Members program, but if you choose to enroll in this study we will collect your Market Member information for the study.

Feedback about the Mobile Market: At follow-up data collection, the surveys will ask for your feedback about your shopping experience. Some people from this group will be asked to complete an additional conversation to offer feedback about your experience with the Mobile Market in person. Conversations will be audio recorded with a digital voice recorder and occur in person or by phone.

What happens if I say “Yes”, but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision.

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Will it cost me anything to participate in this research study?

There will be no cost to you for being in this study.

What happens to the information collected for the research?

Efforts will be made to limit the use of and access to your personal information. It will only be accessed by people with a need to do so for the study. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Additional sharing of your information for mandatory reporting

We will not ask you about child or vulnerable adult abuse, or use of alcohol or use of controlled substance during pregnancy, but if we learn about any of these things happening we may be required or permitted by law or policy to report this information to authorities.

What will be done with my data when this study is over?

We will use and may share data for future research. The data may be shared with researchers/institutions outside of University of Minnesota. We will not ask for your consent before using or sharing these data. We will remove identifiers from your data, which means that nobody who works with the data for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done with data.

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. It is unclear if the Certificate will work in foreign countries.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

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Will anyone besides the study team be at the meeting to go over this document?

You may be asked by the study team for your permission for an auditor to observe the meeting where you review this document and do or do not agree to join the study (or a recording of this meeting). Observing this meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe the meeting (or a recording of the meeting) without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Can I be removed from this research?

You would only be removed from the research without giving your ok if we can no longer reach you, there is inappropriate behavior towards study staff or there are signs of diminished capacity to consent.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study team know right way.

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Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you up to \$220 for your time and effort. The following shows how much we will pay for each step of the study completed:

Study Start	
Surveys and 1 st food interview	\$20
2 nd food interview	\$10
3 rd food interview	\$ 15
Completing fruit and vegetable booklet (per week)	\$ 10 (up to \$40)
All 4 weeks of the booklets turned in	\$ 15
Total possible for study start	\$100

After 6-9 months at follow up	
Surveys and 1 st food interview	\$20
2 nd food interview	\$10
3 rd food interview	\$ 15
Completing fruit and vegetable booklet (per week)	\$ 10 (up to \$40)
All 4 weeks of the booklets turned in	\$ 15
Total possible for follow up	\$100

An additional \$20 will be given to participants selected from the group that gets the Mobile Market right away who complete additional conversations about their experience. We will select participants for this conversation based on how often you shop at the Mobile Market. We want to talk to people who use the Mobile Market a lot and those that don't.

How I get my payments for participation?

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after research steps listed above are completed.

You may use this card at any store that accepts MasterCard or you can use at an ATM to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 6 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name, address, birthdate. They will use this information as part of the payment process. Greenphire will not receive any information about your health status or the study in which you are participating.

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Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

**Yes,
I agree**

**No,
I disagree**

_____ _____ The investigator may take my picture for use in scholarly presentations. My identity may be shared as part of this activity, although the investigator will attempt to limit such identification. I understand the risks associated with such identification.

_____ _____ The investigator may contact me in the future to see whether I am interested in participating in other research studies by Melissa Horning.

Signature to Participate:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

Signature of Participant

Date

Printed Name of Participant

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent

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WITNESS STATEMENT:

The participant was unable to read or sign this consent form because of the following reason:

- ☐ The participant is unable to read the information
- ☐ The participant is visually impaired
- ☐ The participant is physically unable to sign the consent form. Please describe:

☐ Other (*please specify*):

For the Consent of Non-English Speaking Participants when an Interpreter is Used:

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Signature of Interpreter

Date

Printed Name of Interpreter

OR:

Statement from a Witness who is not an Interpreter:

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Signature of Individual

Date

Printed Name of Individual